

IN THE CLAIMS

1. (original) An HIV DNA vaccine composition comprising a nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence; and PLG.

2. (original) The vaccine composition of claim 1, wherein the concentration of PLG is between about 5 and 100 fold greater than the concentration of the nucleic acid expression vector.

3. (original) The vaccine composition of claim 2, wherein the concentration of nucleic acid is between about 10 µg/mL and 5 mg/mL and the concentration of the PLG is between about 100 µg/mL and 100 mg/mL.

4. (original) The vaccine composition of claim 1, wherein the nucleic acid concentration per dose is between approximately 1 µg/dose and 5 mg/dose and the PLG concentration per dose is between approximately 10 µg/dose and 100 mg/dose.

5. (currently amended) The vaccine composition of claim 1, ~~as set forth in Table 1 or Table 2~~ which is an aqueous solution comprising 50.0 mg/ml PLG, 2.0 mg/ml plasmid DNA, 0.5 mg/ml hexadecyltrimethylammonium bromide, 44 mg/ml mannitol, 14.7 mg/ml sucrose, 0.37 mg/ml EDTA, 1.4 mg/ml sodium citrate dihydrate, and 0.04 mg/ml citric acid monohydrate.

6. (currently amended) The vaccine composition of claim 1, comprising 10 µg DNA and 0.25 mg PLG; 100 µg DNA and 2.5 mg PLG; 10µg DNA and 9.25 mg PLG; or 100 µg DNA and 2.5 mg PLG as set forth in column 2 of Table 9.

7. (original) An HIV vaccine composition comprising oligomeric gp140 (o-gp140); and a pharmaceutically acceptable excipient.

8. (original) The HIV vaccine of claim 7, wherein the concentration of o-gp140 is between about 0.1 and 10 mg/mL.

9. (original) The HIV vaccine of claim 7, wherein the concentration of o-gp140 per dose is approximately 100 µg/dose.

10. (original) The HIV vaccine of claim 7, containing:

0.4 mg/ml o-gp140, 2.75 mg/ml sodium citrate dihydrate, 0.15 mg/ml citric acid monohydrate, 17.53 mg/ml sodium chloride;

2 mg Env-DNA/ml, 50 mg PLG/ml, and 2 mg Gag-DNA/ml; or

0.4 mg/ml Env protein and MF59 as set forth in Table 3 or Table 11.

11. (original) The HIV vaccine of claim 7, further comprising an adjuvant.

12. (original) The HIV vaccine of claim 11, wherein the adjuvant is MF59 or CpG.

13. (original) The HIV vaccine of claim 12, wherein the adjuvant is MF59 and MF59 comprises 39 mg/ml squalene, 4.7 mg/ml polysorbate 80, 4.7 mg/ml sorbitan trioleate, 2.68 mg/ml sodium citrate dihydrate, 0.17 mg/ml citric acid monohydrate as set forth in Table 4.

14. (previously presented) An HIV vaccine comprising an HIV Env DNA vaccine composition, said HIV Env DNA vaccine composition comprising at least one HIV Env-encoding sequence and PLG; an HIV Gag DNA vaccine composition, said HIV Gag DNA vaccine composition comprising at least one HIV Gag-encoding sequence and PLG; and an HIV vaccine composition, said HIV vaccine composition comprising oligomeric gp140 (o-gp140) and a pharmaceutically acceptable excipient

15. A method of generating an immune response in a subject, said method comprising:
(a) administering to the subject at least one HIV vaccine composition, said composition comprising: (i) a nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence or (ii) an HIV oligomeric gp 140; and (b) administering to the subject, at a time subsequent to the administering of step (a), at least one HIV vaccine composition, said

composition comprising: (i) a nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence or (ii) an HIV oligomeric up 140.

16. A method of generating an immune response in a subject, said method comprising: (a) administering to said subject at least one HIV DNA vaccine composition comprising a nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence; and (b) administering to the subject, at a time subsequent to the administering of step (a), at least one vaccine composition comprising HIV oligomeric gp140.

17. (previously presented) The method of claim 16, wherein step (a) comprises multiple administrations of said at least one HIV DNA vaccine composition and step (b) comprises multiple administrations of said at least one vaccine composition comprising HIV oligomeric gp 140.

18. (original) The method of claim 17, wherein step (a) comprises two or three administrations at one month intervals; step (b) comprises two or three administrations at 1, 2 or 3 month intervals; and the time between the administrations of step (a) and step (b) is 1 to 5 months.

19. (previously presented) The method claim 16, wherein step (a) comprises administering at least one HIV Gag DNA vaccine and at least one HIV Env DNA vaccine.

20. (previously presented) The method of claim 15 wherein step (b) comprises concurrently administering at least one DNA vaccine comprising a nucleic acid expression vector comprising at least one HIV Gag- or Env-encoding sequence and at least one HIV vaccine comprising oligomeric gp 140.

21. (previously presented) The method of claim 20, wherein step (a) comprises administering at least one HIV Gag DNA vaccine and at least one HIV Env DNA vaccine.

22. (previously presented) The method of claim 15, wherein at least one administration is intramuscular or intradermal.

23. (original) A method of making oligomeric HIV Env gp140 proteins, comprising the steps of introducing a nucleic acid encoding gp140 into a host cell; culturing the host cell under conditions such that gp140 is expressed in the cell; and isolating oligomeric gp140 (o-gp140) protein from the host cell.

24. (original) The method of claim 23, wherein the o-gp140 is secreted from the cell and isolated from the cell supernatant.

25. (previously presented) A method of making an HIV DNA vaccine according to claim 1, comprising the step of combining a nucleic acid expression vector comprising a sequence encoding one or more HIV polypeptides with aseptic PLG microparticles such that the nucleic acid binds to the PLG microparticles to form a DNA/PLG HIV vaccine.

26. (original) The method of claim 25, further comprising the step of lyophilizing the DNA/PLG HIV vaccines.

27. (previously presented) A method of making an HIV vaccine according claim 7, comprising combining o-gp140 with an adjuvant.

28. (previously presented) The HIV vaccine of claim 14, wherein the concentration of PLG is between about 5 and 100 fold greater than the concentration of the nucleic acid expression vector.

29. (previously presented) The HIV vaccine of claim 28, wherein the concentration of nucleic acid is between about 10 µg/mL and 5 mg/mL and the concentration of the PLG is between about 100 µg/mL and 100 mg/mL.

30. (previously presented) The HIV vaccine of claim 14, wherein the concentration of nucleic acid per dose is between approximately 1 µg/dose and 5 mg/dose and the concentration of the PLG per dose is between about 10 µg/dose and 100 mg/dose.

31. (previously presented) The HIV vaccine of claim 14, wherein the HIV Env DNA vaccine composition component ~~is as set forth in Table 1 or column 2 of Table 9;~~

is an aqueous solution comprising 50.0 mg/ml PLG, 2.0 mg/ml plasmid DNA, 0.5 mg/ml hexadecyltrimethylammonium bromide, 44 mg/ml mannitol, 14.7 mg/ml sucrose, 0.37 mg/ml EDTA, 1.4 mg/ml sodium citrate dihydrate, and 0.04 mg/ml citric acid monohydrate; or

comprises:

10 µg DNA and 0.25 mg PLG;

100 µg DNA and 2.5 mg PLG;

10µg DNA and 9.25 mg PLG; or

100 µg DNA and 2.5 mg PLG.

32. (previously presented) The HIV vaccine of claim 14, wherein the HIV Gag DNA vaccine composition component ~~is as set forth in Table 1 or column 2 of Table 9;~~

is an aqueous solution comprising 50.0 mg/ml PLG, 2.0 mg/ml plasmid DNA, 0.5 mg/ml hexadecyltrimethylammonium bromide, 44 mg/ml mannitol, 14.7 mg/ml sucrose, 0.37 mg/ml EDTA, 1.4 mg/ml sodium citrate dihydrate, and 0.04 mg/ml citric acid monohydrate; or

comprises:

10 µg DNA and 0.25 mg PLG;

100 µg DNA and 2.5 mg PLG;

10 µg DNA and 9.25 mg PLG; or

100 µg DNA and 2.5 mg PLG.

33. (previously presented) The HIV vaccine of claim 14, wherein the concentration of o-gp140 is between about 0.1 and 10 mg/mL.

34. (previously presented) The HIV vaccine of claim 14, wherein the concentration of o-gp140 per dose is approximately 100 µg/dose.

35. (previously presented) The HIV vaccine of claim 14, wherein the HIV vaccine composition component contains:

0.4 mg/ml o-gp140, 2.75 mg/ml sodium citrate dihydrate, 0.15 mg/ml citric acid monohydrate, 17.53 mg/ml sodium chloride;

2 mg Env-DNA/ml, 50 mg PLG/ml, and 2 mg Gag-DNA/ml; or

0.4 mg/ml Env protein and MF59 is as set forth in Table 3 or Table 11.

36. (previously presented) The HIV vaccine of claim 14, wherein the HIV vaccine composition component further comprising an adjuvant.

37. (previously presented) The HIV vaccine of claim 36, wherein the adjuvant is MF59 or CpG.

38. (previously presented) The HIV vaccine of claim 37, wherein the adjuvant is MF59 and MF59 comprises 39 mg/ml squalene, 4.7 mg/ml polysorbate 80, 4.7 mg/ml sorbitan trioleate, 2.68 mg/ml sodium citrate dihydrate, 0.17 mg/ml citric acid monohydrate is as set forth in Table 4.

39. (previously presented) The method of claim 16, wherein at least one administration is intramuscular or intradermal.

40. (new) The HIV DNA vaccine composition of claim 1 further comprising an adjuvant.

41. (new) The HIV DNA vaccine composition of claim 40 wherein the adjuvant is an oil in water emulsion comprising 39 mg/ml squalene, 4.7 mg/ml polysorbate 80, 4.7 mg/ml sorbitan trioleate, 2.68 mg/ml sodium citrate dihydrate, 0.17 mg/ml citric acid monohydrate.